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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-0109]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Respiratory Protective Devices—42 CFR part 84—Regulation—(0920-0109) — Revision — National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection was formerly named Respiratory Protective Devices 30 CFR part 11 but in 1995, the respirator standard was moved to 42 CFR Part 84. The regulatory authority for the National Institute for Occupational Safety and Health (NIOSH) certification program for respiratory protective devices is found in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 577a, 651 et seq., and 657(g)) and the Occupational Safety and Health Act of 1970 (30 U.S.C. 3, 5, 7, 811, 842(h), 844). These regulations have, as their basis, the performance tests and criteria for approval of respirators used by millions of American construction workers, miners, painters, asbestos removal workers, fabric mill workers, and fire fighters.

Regulations of the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH-approved respirators. These regulations also establish methods for respirator manufacturers to submit respirators for testing under the regulation and have them certified as NIOSH-approved if they meet the criteria given in the above regulation.

NIOSH, in accordance with 42 CFR Part 84: (1) issues certificates of approval for respirators which have met specified construction, performance, and protection

requirements; (2) establishes procedures and requirements to be met in filing applications for approval; (3) specifies minimum requirements and methods to be employed by NIOSH and by applicants in conducting inspections, examinations, and tests to determine effectiveness of respirators; (4) establishes a schedule of fees to be charged applicants for testing and certification, and (5) establishes approval labeling requirements. Information is collected from those who request services under 42 CFR Part 84 in order to properly establish the scope and intent of request.

Information collected from requests for respirator approval functions includes contact information and information about factors likely to affect respirator performance and use. Such information includes, but is not necessarily limited to, respirator design, manufacturing methods and materials, quality assurance plans and procedures, and user instruction and draft labels, as specified in the regulation.

The main instrument for data collection for respirator approval functions is the Standard Application for the Approval of Respirators (SAF), currently Version 7. A replacement instrument which will collect the same information is in development.

Respirator manufacturers are the respondents (estimated to average 63 each year over the years 2014-2016) and upon completion of the SAF their requests for approval are evaluated. The applications are submitted at will and the most reasonable prediction of respondents is the number from the most recent year, 63 in 2013. The decrease is likely due to random fluctuations and changes in business conditions. No survey was conducted to more thoroughly analyze the reasons for the change in number of respondents. Although there is no cost to respondents to submit other than their time to participate, respondents requesting respirator approval are required to submit fees for necessary testing as specified in 42 CFR Parts 84.20-22, 84.66, 84.258 and 84.1102. In calendar year 2013 \$449,610 was accepted.

Applicants are required to provide test data that shows that the manufacturer is capable of ensuring that the respirator is capable of meeting the specified requirements in 42 CFR Part 84. The requirement for submitted test data is likely to be satisfied by standard testing performed by the manufacturer, and is not required to follow the relevant NIOSH Standard Test Procedures. As additional testing is not required, providing

proof that an adequate test has been performed is limited to providing existing paperwork.

42 CFR Part 84 approvals offer corroboration that approved respirators are produced to certain quality standards. Although 42 CFR Part 84 Subpart E prescribes certain quality standards, it is not expected that requiring approved quality standards will impose an additional cost burden over similarly effective quality standards that are not approved under 42 CFR Part 84.

Manufacturers with current approvals are subject to site audits by the Institute or its agents under 42 CFR Part 84.43. There is no fee or form associated with audits. Audits may occur periodically or as a result of a reported issue. Sixty site audits were scheduled for the 2013 calendar year. The total request burden hours are 102,429.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Business or other for-profit	Standard Application for the Approval of Respirators Version 7 and Version 8	63	7	229

Business or other for- profit	Audit (42 CFR 84.43)	60	1	24
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Leroy Richardson
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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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